**Authority:** Secs. 201, 306, 401, 403, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 336, 341, 343, 371).

2. Section 130.10 is added to subpart A to read as follows:

**§ 130.10 Requirements for substitute foods named by use of a nutrient content claim and a standardized term.**

(a) *Description.* The foods prescribed by this general definition and standard of identity are those foods that substitute (see § 101.13(d) of this chapter) for a standardized food defined in parts 131 through 169 of this chapter but that do not comply with the standard of identity because of a deviation that is described by a nutrient content claim that has been defined by FDA regulation. The nutrient content claim shall comply with the requirements of § 101.13 of this chapter and with the requirements of the regulations in part 101 of this chapter that define the particular nutrient content claim that is used. The food shall comply with the relevant standard in all other respects except as provided in paragraphs (b) and (d) of this section.

(b) *Nutrient addition.* Nutrients shall be added to the food to restore nutrient levels so that the product is not nutritionally inferior, as defined in § 101.3(e) (4) of this chapter, to the standardized food as defined in parts 131 through 169 of this chapter. The addition of nutrients shall be reflected in the ingredient statement.

(c) *Performance characteristics.* The performance characteristics (e.g., physical properties, flavor characteristics, functional properties, shelf life) of the food shall be similar to those of the standardized food as produced under parts 131 through 169 of this chapter, except that if there is a significant difference in performance characteristics, the label shall include a statement informing the consumer of such difference (e.g. if appropriate, "not recommended for cooking"). Such statement shall appear on the principal display panel within the bottom 30 percent of the area of the label panel with appropriate prominence, in type which shall be no less than onehalf the size of the type used in such claim but no smaller than one-sixteenth of an inch.

(d) *Other ingredients.* (1) Ingredients used in the product shall be those ingredients provided for by the standard as defined in parts 131 through 169 of this chapter and in paragraph (b) of this section, except that safe and suitable ingredients to improve texture, add flavor, prevent syneresis, or extend shelf life may be used so that the product is not inferior in performance characteristics to the standardized food defined in parts 131 through 169.

(2) An ingredient or component of an ingredient that is specifically required by the standard as defined in parts 131 through 169 of this chapter, shall not be replaced or exchanged with a similar ingredient from another source unless the standard, as defined in parts 131 through 169, provides for the addition of such ingredient (e.g., vegetable oil shall not replace milkfat in light sour cream).

(3) An ingredient or component of an ingredient that is specifically prohibited by the standard as defined in parts 131 through 169 of this chapter, shall not be added to a substitute food under this section.

(e) *Nomenclature.* The name of a substitute food that complies with all parts of this regulation is the appropriate nutrient content claim and the applicable standardized term.

(f) *Label declaration.* (1) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

(2) Ingredients not provided for, and ingredients used in excess of those provided for, by the standard as defined in parts 131 through 169 of this chapter, shall be identified as such with an asterisk in the ingredient statement, except that ingredients added to restore nutrients to the product as required in paragraph (b) of this section shall not be identified with an asterisk. The statement "*Ingredient(s) not in regular _____" (fill in name of the traditional standardized food) or "*Ingredient(s) in excess of amount permitted in regular _____" (fill in name of the traditional standardized food) or both as appropriate shall immediately follow the ingredient statement in the same type size.

**David A. Kessler,**

*Commissioner of Food and Drugs.*

**Louis W. Sullivan,**

*Secretary of Health and Human Services.*

Dated: November 4, 1991.

[FR Doc. 91-27170 Filed 11-26-91; 8:45 am]

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**21 CFR Part 101**

**[Docket No. 91N-0344]**

**RIN 0905-AD08**

## Food Labeling: Use of Nutrient Content Claims For Butter

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to adopt a regulation that will permit the use of nutrient content claims ("descriptors") that are defined by regulation in 21 CFR part 101 to be made for butter. This action is in response to the Nutrition Labeling and Education Act of 1990 (the 1990 amendments). FDA believes that the proposed regulation will provide the consumer with a selection of modified butter products that are informatively labeled and will promote honesty and fair dealing in the interest of consumers.

**DATES:** Written comments by February 25, 1992. The agency is proposing that any final rule that may issue based upon this proposal become effective 6 months following its publication in accordance with requirements of the Nutrition Labeling and Education Act of 1990.

**ADDRESSES:** Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Shellee A. Davis, Center for Food Safety and Applied Nutrition (HFF-414), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-485-0112.

**SUPPLEMENTARY INFORMATION:**

### I. Background

*A. The Situation With Respect to Butter—The Act of March 4, 1923—Sections 201a and 401 of the Federal Food, Drug, and Cosmetic Act*

The Act of August 2, 1886 (24 Stat. 209), defined "butter" as:

* * * the food product usually known as butter, and which is made exclusively from milk or cream, or both, with or without common salt, and with or without additiona coloring matter.

The Act of March 4, 1923 (21 U.S.C. 321a) amended the Act of August 2, 1886, by adding the requirement that butter must contain not less than 80 percent by weight of milkfat. FDA has not established any further standards o identity concerning butter because section 401 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 341) specifically states that "no definition and standard of identity and no standard of quality shall be established for * * * butter."

*B. Pending Petitions*

Johanna Farms, Inc., Flemington, NJ 08822, submitted a citizen petition, dated April 9, 1990 (Docket No. 90P-0141), requesting that FDA establish, by regulation, a common or usual name for

"light butter." Johanna Farms, Inc., is engaged in the dairy business throughout the northeastern and mid-Atlantic United States. Johanna Farms, Inc., stated in its petition that a common or usual name definition for light butter would: (1) Further the public health interest in reduced fat consumption; (2) further the public interest in calorie reduction; (3) respond to consumer demand; (4) provide a term that is truthful, adequately informative, and not misleading; and (5) be consistent with the statutory definition of butter. Because this petition was filed before the passage of the 1990 amendments, FDA is responding to it in this proposal.

FDA published a notice in the **Federal Register** on March 14, 1991 (56 FR 10906) advising, in part, that it is likely to deny, without prejudice, any health claim or descriptor petition submitted under the 1990 amendments until the agency has promulgated final procedural regulations concerning the submission and content of such petitions. Therefore, FDA has not considered any of the petitions on modified butter products that have been submitted since the passage of the 1990 amendments in developing this proposal. FDA, however, encourages these petitioners and all interested persons to comment on this proposal and on the other descriptor proposals published elsewhere in this issue of the **Federal Register**.

*C. The 1990 Amendments*

On November 8, 1990, the President signed into law the 1990 amendments (Pub. L. 101-535). Section 3(b)(1)(A) of the 1990 amendments requires that FDA issue regulations that define claims that characterize the level of nutrients that are of the type that are required to be declared in nutrition labeling. Specifically, FDA was directed to promulgate regulations prescribing the use of the terms "free," "low," "light" or "lite," "reduced," "less," and "high" to characterize the level of these nutrients, unless the Secretary finds that the use of any such term would be misleading (section 3(b)(1)(A)(iii) of the 1990 amendments). Regulations prescribing general requirements for the use of nutrient content claims and defining specific descriptors are proposed in other documents published elsewhere in this issue of the **Federal Register**. Section 3(b)(1)(A)(viii) of the 1990 amendments authorizes FDA to issue regulations to permit the use of nutrient content claims for butter.

The legislative history of the 1990 amendments, specifically the House of Representatives Report 101-538, 101st Cong., 2d sess. 22-23 (June 13, 1990), states that while the Committee on Energy and Commerce believed that FDA has authority under current law to permit nutrient content claims on butter products, the 1990 amendments "explicitly [permit] the Secretary to allow a claim described in section 403(r)(1)(A) of the act (such as 'light') to be made for butter." The House Report goes on to state that "[i]n issuing regulations for claims concerning fat, calories, and other nutrients in butter, the Secretary should consider arguments concerning the appropriate characteristics of butter." (*Id.*, at 23.) This proposal gives interested persons the opportunity to present their views on this issue.

## II. The Proposal

*A. Tentative Finding that Providing for the Use of Nutrient Content Claims for Butter Will Assist Consumers in Maintaining Healthy Dietary Practices*

FDA believes that the use of nutrient content claims for butter will assist consumers in maintaining healthy dietary practices. "The Surgeon General's Report on Nutrition and Health" (Ref. 1) emphasizes the need for most people to reduce their consumption of fat, saturated fat, and cholesterol and to achieve and maintain a desirable body weight. It states that heart disease, cancer, and stroke are the three leading causes of death in the United States, and that diet plays a part in the development of these conditions as well as other chronic health problems, such as atherosclerosis, high blood pressure, diabetes mellitus, obesity, osteoporosis, dental diseases, and diverticular disease. A product that has been modified to have significantly lower levels of fat, saturated fat, sodium, or cholesterol so that it can bear nutrient content claims will, therefore, be of nutritional benefit to consumers.

FDA notes that there is consumer demand to purchase modified dairy products. Under 21 CFR 130.17, FDA has issued temporary marketing permits for light sour cream, light ice cream, nonfat cottage cheese, and light eggnog. FDA has also granted temporary marketing permit extensions for light sour cream and light eggnog. The manufacturers submitting the applications for the extensions included information gathered under their market tests that shows a high level of consumer acceptance of those products.

*B. FDA's Traditional View of How Modified Butter Products Must Be Labeled and the Effect of the 1990 Amendments*

Congress provided the definition for "butter" in section 201a of the act to protect consumers from butter-like products that were inferior to the butter that they expected to purchase. Consistent with this, one of the main purposes of the act is to protect consumers from economic deception. A product using the term "butter" must comply with the statutory definition of butter, or its labeling would be false, and it would be misbranded under section 403(a)(1) of the act (21 U.S.C. 343(a)(1)). A food sold under the name "butter" that does not comply with the statutory standard for butter also is in violation of section 403(b) of the act (21 U.S.C. 343(b)) in that it is sold under the name of another food. These provisions apply to all foods defined by a standard of identity.

Therefore, a food whose statement of identity includes a term that is defined by a food standard purports to be that standardized food and must comply with the applicable standard. The effect of this requirement, however, is that a product labeled as, for example, "light butter" because it contains less fat and calories than regular butter, or a product labeled as "light sour cream" because it contains less fat and calories than regular sour cream, would be misbranded because it does not meet the applicable standard.

The maker of the "light sour cream" product has had an alternative, however. It has been able to submit a petition for a new food standard that will define "light sour cream" as a different product than "sour cream." Moreover, it could obtain a temporary marketing permit, as several manufacturers have, that will allow it to market the product while it develops its petition, and the petition is reviewed by FDA.

The maker of the "light butter" product, however, has had no such option. As stated above, section 401 of the act prohibits FDA from establishing any new standards for foods that purport to be butter.

Consequently, modified butter products have been sold under a common or usual name such as "dairy spread," along with appropriate labeling that accurately informs the consumer as to what the product is but that does not represent it to be butter. Modified butter products that are nutritionally inferior (as defined in § 101.3(e) (21 CFR 101.3(e))) to butter are sold as "imitation butter."

To provide some relief in this situation, Congress passed section 3(b)(1)(A)(viii) of the 1990 amendments. While this section does not directly address the prohibition in section 401 of the act, it clearly evidences an intent by

Congress to permit nutrient content claims like "light" to be made for butter. This provision was discussed by Congressman Torricelli and Congressman Waxman, a sponsor of the bill that became the 1990 amendments.

Mr. Torricelli * * *

My inquiry is whether it would be within the authority of the FDA under the language we have been discussing to authorize the marketing of a product called lite butter that achieved * * * 35 to 40 percent milkfat, and with a third less calories as long as it were not nutritionally inferior and kept other characteristics of butter and were properly labeled * * *.

Mr. Waxman * * *

[I]t would be in the FDA's discretion to determine the characteristics of light butter. (Congressional Record, H5845, July 30, 1990.)

It is FDA's job to read section 3(b)(1)(A)(viii) of the 1990 amendments and section 401 of the act together and to develop an interpretation that gives effect to both provisions. Thus, proposed § 101.67 focuses not on the ingredients that may be used in a butter product, as a standard would, but rather, as section 3(b)(1)(A)(viii) of the 1990 amendments does, on the circumstances in which nutrient content claims may be used. While the proposed regulation, in § 101.67(a)(2), does list the ingredients of the food, this list is essentially the same as that in section 201a of the act, with two small additions that reflect Congress's intent in passing the 1990 amendments and that do not represent a change from the statutory standard. FDA believes that its proposed approach harmonizes section 3(b)(1)(A)(viii) of the 1990 amendments and section 401 of the act. The agency requests comments on its approach.

*C. FDA's Proposed Regulation*

In response to section (3)(b)(1)(a)(viii) of the 1990 amendments, FDA is proposing to permit nutrient content claims to be made for butter. Under proposed § 101.67(a), such claims may be made if the product meets the applicable definition of the nutrient content claims, it complies with certain content requirements that assure that it can fairly be characterized as "butter," and it is not nutritionally inferior to butter as butter would be produced under section 201a of the act. In addition, FDA is proposing to require that the product that bears the nutrient content claims have similar performance characteristics to butter, and that to the extent it does not, this fact is disclosed with appropriate prominence in the labeling. Each of these proposed requirements is discussed in more detail below.

1. The Nutrient Content Claim

Proposed § 101.67(a)(1) provides that a butter product may bear a nutrient content claim if it complies with both the general requirements for nutrient content claims in § 101.13 and the requirements for use of the particular nutrient content claim that is to be applied to the product.

Section 101.13, as proposed elsewhere in this issue of the **Federal Register**, prescribes the circumstances in which claims that characterize the level of a nutrient in a food may be made on a food label or in labeling. Proposed § 101.13(b) limits the claims that can be used to expressly or by implication characterize the level of a nutrient (nutrient content claim) of the type required to be declared in nutrition labeling pursuant to § 101.9 to those that have been defined by FDA by regulation.

To prevent consumer deception as a result of a manufacturer reducing the serving size and, thereby, the milkfat content per serving, FDA is proposing that the serving size for butter that is to bear a nutrient content claim must be the same as that established for regular butter. (See proposed § 101.12(g).) On July 19, 1990 (55 FR 29517), FDA published a proposal to establish serving sizes for 159 food product categories and proposed the standard serving size for butter and modified versions of butter as 1 tablespoon. FDA is retaining these amounts in its reproposal of its serving size regulations published elsewhere in this issue of the **Federal Register** as part of its food labeling initiative to implement the provisions of the 1990 amendments.

The agency is defining in proposals published elsewhere in this issue of the **Federal Register** the terms "free,. "low," "light" or "lite," "reduced," and "high." In addition, FDA is proposing to define the terms "very low" (for sodium only) and "source" and to make provision for the use of comparative statements using the terms "less," "fewer," and "more" because the agency has tentatively concluded that they would be useful in helping consumers choose a healthy diet.

For example, under proposed § 101.62 concerning fat claims, which is published elsewhere in this issue of the **Federal Register**, a product must be formulated to have a significant reduction in fat content (50 percent) to bear a "reduced fat" descriptor. A product that contains only slightly less (e.g., 10 percent) fat than the regular version of the product could not bear such a claim.

To avoid consumer confusion, FDA believes that the principal display panel of the label should clearly state the difference between butter as defined in section 201a of the act and the product that bears the nutrient content claim. Thus, in proposed § 101.67(a)(1), FDA is requiring, in accordance with proposed §§ 101.13 and 101.62(b)(4)(ii), that for example, if a .reduced fat" claim is made, a truthful comparative statement must appear in immediate proximity to the most prominent use of the claim (e.g., the statement of identity). The comparative statement would disclose the percentage difference between the level of milkfat in the product that bears the claim and 80 percent milkfat, which is the level specified for butter in section 201a of the act and which FDA is proposing, in § 101.67(a)(1), to use as the basis for calculating milkfat reductions. Proposed § 101.62 also requires that the comparative statement include quantitative information comparing the actual amount of fat in a serving of the butter for which the claim is made to the amount in regular butter. For example, a product that contains 40 percent milkfat could be labeled "reduced fat butter" and bear, in immediate proximity to the name, the statement: .Contains 50 percent less fat than regular butter. Fat content has been reduced from 12 grams to 6 grams per serving."

FDA advises that under proposed § 101.62(d)(4), which defines cholesterol claims, reducing the cholesterol content of butter will not justify a reduced cholesterol claim because of the high saturated fat content of butter. Comments on the impact of cholesterol claim restrictions on butter labeling should be directed to docket numbers 84N-0153 and 90N-0256 pertaining to the proposed descriptor regulations for fats and cholesterol published elsewhere in this issue of the **Federal Register**.

As provided in the statutory standard, salt is an optional ingredient in butter. Thus, under proposed § 101.67, sodium and salt content nutrient content claims that are truthful and in accordance with proposed §§ 101.13 and 101.61 may also be used for butter.

2. "Butter"

As a condition for the use of a nutrient content claim on butter, the product that is to bear the nutrient content claim must not only satisfy the requirements for the claim, it must also be fairly described as "butter." The characterizing component of butter is milkfat. Under section 201a of the act, "butter" must contain at least 80 percent milkfat.

The legislative history of the 1990 amendments makes clear, however, that Congress intended to authorize FDA to permit the use of nutrient content claims on butter products that contain less than 80 percent fat. (H. Rept. 101–538, 101st Cong., 2d sess. 23.) As stated above, in floor debate preceding passage of the 1990 amendments in the House, a Congressman asked one of the sponsors of the bill whether it would permit FDA to allow a product that contains 35 or 40 percent milkfat to be called "lite butter." The response was that it would. (Congressional Record H5844, July 30, 1990).

Therefore, in § 101.67(a)(2), FDA is proposing to permit the use of the term "butter" in conjunction with a nutrient content claim if the product that bears the nutrient content claim is made from the ingredients and constituents of the ingredients listed in section 201a of the act, but the agency is not proposing to require that the product contain a particular level of milkfat. FDA believes that this proposed action is consistent with congressional intent.

In the House Report, Congress directed FDA to consider arguments concerning the appropriate characteristics of butter. In a footnote, the Report continued:

> The Committee is aware that the dairy industry takes the position that products containing less than approximately 50 percent milkfat lose some of the characteristics of butter. In connection with the promulgation of the regulations, representatives of dairy interests and health experts will have the opportunity to present their views on the issue to the Secretary. (H. Rept. 101–538, 101st Cong., 2d sess. 23. n. 3.)

FDA requests comments on whether its tentative decision not to include a minimum milkfat level in § 101.67 is appropriate.

FDA is proposing to add two types of ingredients to the list of ingredients that derives from section 201a of the act. First, to ensure that a butter product that bears a nutrient content claim is not nutritionally inferior to butter that is produced under section 201a of the act, FDA is proposing to permit the addition of nutrients to the product. The legislative history makes clear that Congress anticipated that a butter product that bears a nutrient content claim would not be nutritionally inferior to butter. (Congressional Record H5845, July 30, 1990.)

Secondly, FDA is proposing to permit the use of safe and suitable bacterial cultures. The agency is doing so for two reasons. First, butter has historically been a cultured product. When the Act of August 2, 1886 was passed, milk and cream used in the manufacture of butter were permitted to sour spontaneously or by the addition of a starter of soured milk or cream prior to churning (Ref. 2). Thus, FDA is merely conforming proposed § 101.67 to the way that butter has traditionally been produced. Secondly, in the floor debate that preceded the House passage of the 1990 amendments, a sponsor of the bill in the House agreed that under the language of the bill, it would be within the FDA s authority to grant the Johanna Farms, Inc., petition. (Congressional Record H5844.) The petition specifically provides for the use of safe and suitable bacterial cultures.

FDA realizes that manufacturers may want to use ingredients that are not listed in § 101.67(a)(2) to yield an acceptable "butter" product. Therefore, FDA is requesting comment on whether it should provide for the use of safe and suitable nondairy ingredients to improve texture, prevent syneresis, add flavor, or extend the shelf life in § 101.67(a)(2). FDA is also requesting comment concerning the addition of water instead of skim milk, whey, or milk, as an ingredient in butter products to replace the milkfat. If comments support the use of safe and suitable nondairy ingredients and provide a substantial basis for their use, FDA may provide for the use of these ingredients in any final rule based on this proposal.

Under proposed § 101.67(c), each of the ingredients that is used in the butter for which a claim is made must be declared on the label as required by the applicable sections of 21 CFR part 101. According to § 101.4, all ingredients must be listed by common or usual name in descending order of predominance by weight on either the principal display panel or the information panel.

3. Nutritional Inferiority

FDA is proposing to specifically require in § 101.67(a)(3) that a product that bears a nutrient content claim not be nutritionally inferior to standardized butter. A modified butter product that is nutritionally inferior to butter would be an imitation food under § 101.3(e)(1) and thus subject to the requirements of section 403(c) of the act. In § 101.3(e)(4)(i), FDA defines nutritional inferiority as any reduction in the content of an essential nutrient that is present in the food imitated in a measurable amount. In § 101.3(e)(4)(ii), FDA has defined a measurable amount of an essential nutrient in a food as 2 percent or more of the U.S. Recommended Daily Allowance (U.S. RDA) of protein or any vitamin or mineral listed under current § 101.9(c)(7)(iv) per average or usual serving or, where the food is customarily not consumed directly, per average or usual portion, as established in § 101.9. FDA is proposing in the document on mandatory nutrition labeling published elsewhere in this issue of the **Federal Register** to establish Reference Daily Intakes (RDI's) for use in declaring nutrient content in nutrition labeling and to replace the current U.S. RDA's with the RDI's. If FDA adopts that proposal, nutritional equivalence will be based on the established RDI.

Butter is a significant source (as defined in current § 101.9(c)(7)(v)) of fat soluble vitamins such as vitamin A. A 1-tablespoon serving of butter provides 10 percent of the U.S. RDA for vitamin A. Any reduction in the amount of milkfat also reduces the amount of vitamin A and other fat soluble vitamins per serving. Therefore, FDA believes that vitamin A and other essential nutrients must be added to restore nutrients to products using the term "butter" in their name. Given Congress's intent to provide for butter products with modified milkfat levels (Congressional Record H5844, July 30, 1990), FDA believes it is appropriate to provide for the addition of such nutrients, even though the statutory standard for butter does not provide for the addition of those ingredients.

4. Performance Characteristics

FDA believes that consumers expect that a product bearing the term "butter" will resemble butter and perform like butter. Therefore, in order to not mislead consumers, FDA believes that a product bearing the term "butter" in its identity statement should meet these expectations. The relevant performance characteristics include physical properties (e.g., melting point), organoleptic characteristics (e.g., texture, aroma, and taste), functional properties (e.g., spreadability), and shelf life.

FDA recognizes, however, that it may not be possible or practical to produce a product that meets the requirements for a fat claim and that performs similarly to butter in all respects. Therefore, to assure that consumers are not misled as to the characteristics of the product, FDA is proposing in § 101.67(b) to require that the label include a statement informing the consumer of any significant differences in performance characteristics between a product that bears a nutrient content claim and standardized butter.

For example, reduced fat butter may not perform the same as standardized butter when used as an ingredient in

baked goods, and if this proposal is adopted, a statement such as "not recommended for baking purposes" will have to appear on the label of the former product. Under 403(f) of the act, FDA believes that the statement must appear on the label with such conspicuousness and in such terms as to render it likely to be read and understood by the consumer under customary conditions of purchase and use. FDA believes that the statement must appear in the same area of the label as the statement of identity for the product so that the consumer will know where to find such information. Therefore, FDA is proposing in § 101.67(b) to require that this statement appear on the principal display panel within the bottom 30 percent of the area of the label panel with appropriate prominence, that is, it shall be in type no less than one half the size of the type of the most prominent nutrient claim on the panel but no smaller than one-sixteenth of an inch.

The agency tentatively concludes that this information about the performance characteristics of the product is a material fact under section 201(n) of the act because it bears on the consequence of the use of the article. Accordingly, this information must be communicated to the consumer on the product label, or the labeling would be misleading, and the product would be misbranded under section 403(a) of the act. FDA is requesting comments concerning what performance characteristics butter that bears a claim may possess and still be considered to perform like standardized butter.

*D. Conclusion*

FDA believes that descriptors should be used to make available to the consumer informatively labeled products and to aid the consumer by providing a larger variety of products to meet nutritional goals. FDA is issuing this proposal in furtherance of these objectives as well as to implement section 3(b)(1)(A)(viii) of the 1990 amendments and to respond to the Johanna Farms, Inc., petition. FDA requests comments on the appropriateness of its approach and on alternative approaches that are more appropriate to attain these objectives.

III. Economic Impact

FDA has examined the economic implications of the proposed rule pertaining to 21 CFR Part 101 requirements as required by Executive Order 12291 and the Regulatory Flexibility Act. Executive Order 12291 compels agencies to use cost-benefit analysis as a component of decisionmaking and the Regulatory Flexibility Act requires regulatory relief for small businesses where feasible.

FDA is proposing changes to the food label that will, for the most part, codify changes mandated by the 1990 amendments. The agency has prepared a regulatory impact analysis (RIA) to determine the economic effects of this and other proposed labeling rules which amend food labeling regulations under 21 CFR part 101. This proposed action will provide consumers with a selection of butter products that are informatively labeled.

Because there are no additional costs to manufacturers to comply with this proposed regulation, FDA concludes that this is not a major rule as defined by Executive Order 12291. In addition, FDA certifies that this action will not result in a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act.

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Comments

Interested persons may, on or before February 25, 1992, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

In accordance with section 3(b)(1)(B) of the 1990 amendments, FDA must issue by November 8, 1992, final regulations permitting nutrient content claims for butter. If the agency does not promulgate final regulations by November 8, 1992, section 3(b)(2) of the 1990 amendments provides that the regulations proposed in this document shall be considered as the final regulations. The agency has determined that 90 days is the maximum time that it can provide for the submission of comments and still meet this statutory timeframe for the issuance of final regulations. Thus, the agency is advising that it will not consider any requests under 21 CFR 10.40(b) for extension of the comment period beyond February 25, 1992. The agency must limit the comment period to no more than 90 days to assure sufficient time to develop a final rule based on this proposal and the comments it receives.

VI. References

The following information has been placed on display in the Dockets Management Branch (address above), and may be seen by interested persons between 9 a.m. and 4 p.m. Monday through Friday.

1. U.S. Department of Health and Human Services, Public Health Service, "The Surgeon General's Report on Nutrition and Health, "DHHS (PHS) Publication No. 88-50210 (GPO Stock No. 017-001-00465-1), U.S. Government Printing Office, Washington, DC, 1988.

2. U.S. Department of Justice opinion letter, from Harris M. Daugherty, U.S. Attorney General to the U.S. Secretary of the Treasury Department, August 12, 1921.

**List of Subjects in 21 CFR Part 101**

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 101 be amended as follows:

**PART 101—FOOD LABELING**

1. The authority citation for 21 CFR part 101 continues to read as follows:

**Authority:** Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.67 is added to Subpart D to read as follows:

**§ 101.67 Use of nutrient content claims for butter.**

(a) Claims may be made to characterize the level of nutrients, including fat, in butter if:

(1) The claim complies with the requirements of § 101.13 and with the requirements of the regulations in this part that define the particular nutrient content claim that is used and how it is to be presented. In determining whether a claim is appropriate, the calculation of the percent fat reduction in milkfat shall be based on the 80 percent milkfat requirement provided by the statutory standard for butter (21 U.S.C. 321a);

(2) The product contains cream or milk, including milk constituents (including, but not limited to, whey, casein, modified whey, and salts of casein), or both, with or without added salt, with or without safe and suitable colorings, with or without nutrients

added to comply with paragraph (a)(3) of this section, and with or without safe and suitable bacterial cultures; and

(3) The product is not nutritionally inferior, as defined in § 101.3(e)(4), to butter as produced under 21 U.S.C. 321a.

(b) The performance characteristics (e.g., physical properties, organoleptic characteristics, functional properties, shelf life) of the product shall be similar to butter as produced under 21 U.S.C. 321a. If there is a significant difference in performance characteristics, the label shall include a statement informing the consumer of such difference (e.g., if appropriate, "not recommended for baking purposes"). Such statement shall appear on the principal display panel within the bottom 30 percent of the area of the label panel in type that shall be no less than ½ the size of the type used for such claim but no smaller than 1/16 of an inch.

(c) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of this part.

Dated: November 4, 1991.

**David A. Kessler,**

*Commissioner of Food and Drugs.*

**Louis W. Sullivan,**

*Secretary of Health and Human Services.*

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## 21 CFR Part 100

**[Docket No. 91N-0038]**

**RIN 0905-AD08**

## State Petitions Requesting Exemption From Federal Preemption

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to provide for petitions requesting exemption from preemption for certain State or local food standards and other labeling requirements that are preempted under the provisions of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments). The proposed regulations set out the procedures for the submission, and for agency review, of these petitions, and the information that the petitioner should supply. Petitions by State and local governments seeking exemption from specified preemptive Federal requirements are specifically authorized by the 1990 amendments.

**DATES:** Written comments by February 25, 1992. The agency is proposing that any final rule that may issue based upon this proposal become effective November 8, 1992, or 30 days after date of publication in the **Federal Register**, if earlier.

**ADDRESSES:** Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, 301-443-1751.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth J. Campbell, Center for Food Safety and Applied Nutrition (HFF-312), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-485-0229.

**SUPPLEMENTARY INFORMATION:**

### I. Background

*A. Federal Labeling Requirements Made Preemptive by the Nutrition Labeling and Education Act of 1990*

The Nutrition Labeling and Education Act of 1990 (Pub. L. 101-535) (the 1990 amendments) amends the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.*) (the act) to provide, among other things, for Federal preemption of certain food standards and labeling requirements issued by a State or a political subdivision of a State (hereinafter referred to collectively as "State"). Section 6(a) of the 1990 amendments adds section 403A to the act (21 U.S.C. 343-1) which provides that after the effective date of the operative provisions (prescribed in section 10(b) of the 1990 amendments), no State may directly or indirectly establish under any authority, or continue in effect as to any food in interstate commerce, any of the following types of requirements:

1. Any requirement for a food that is the subject of a standard of identity established under section 401 of the act (21 U.S.C. 341) that is not identical to such standard of identity or that is not identical to the requirements of section 403(g) of the act (21 U.S.C. 343(g)). Section 403(g) of the act states that a food is misbranded if it purports to be or is represented as a food for which a definition and standard of identity has been established under section 401 of the act, unless it conforms to the definition and standard, and its label bears the name of the food specified in the definition and standard. Preemption of this type of requirement became effective on November 8, 1990, the date of enactment of the 1990 amendments (section 10(b)(1)(A) of the 1990 amendments).

2. Any requirement for the labeling of foods that relates to use of the term "imitation" that is not identical to the requirements of section 403(c) of the act; any requirement for label information identifying the manufacturer, packer, or distributor and the quantity of contents, that is not identical to the requirements of section 403(e) of the act; and any requirement concerning the listing on the label of ingredients that is not identical to the requirements of section 403(i)(2) of the act. Preemption of these types of requirements (section 403A(a)(2) of the act) will take effect on November 8, 1991, 1 year after the date of the enactment of the 1990 amendments (section 10(b)(1)(B) of the 1990 amendments).

3. Any requirement for the labeling of food that is offered for sale under the name of another food that is not identical to the requirements of section 403(b) of the act; any requirement concerning a container that is so made, formed, or filled as to be misleading that is not identical to the requirements of section 403(d) of the act; any requirement concerning the prominence of required information on the label that is not identical to the requirements of section 403(f) of the act; any requirement concerning the labeling of a food purporting to be or represented as a food for which a standard of quality or a standard of fill has been established under section 401 of the act that is not identical to the requirement of section 403(h) of the act; any requirement that the label of a food bear the common or usual name of the food that is not identical to the requirements of section 403(i)(1) of the act; and any requirement that the label states whether a food contains any artificial flavoring, artificial coloring, or a chemical preservative that is not identical to the requirements of section 403(k) of the act Under section 6(b) of the 1990 amendments, these six provisions (section 403A(a)(3) of the act) do not become preemptive until FDA determines that each is being adequately implemented by Federal regulations (see section 403(A)(a) of the act and section 10(b)(1)(C) of 1990 amendments).

Whether there is adequate implementation of the State and Federal requirements of the type addressed in section 403A(a)(3) of the act is being studied by the Committee on State Food Labeling of the National Academy of Sciences (the committee), Institute of Medicine, Food and Nutrition Board (56 FR 21388, May 8, 1991 (and 56 FR 55130, October 24, 1991)). Although the 1990 amendments state that the contract shall provide for completion of the committee's study by May 8, 1991, completion of the study and the committee's report has been delayed by unforeseen circumstances (56 FR 21388,